

OMEPRAZOL POLVO (EUR. PH.)

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|----------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 151367 | CAS Nº: 73590-58-6 | ANALYSIS Nº: 002/25 |
| MANUFACTURER BATCH: OME/E-261/24 | CERTIFICATE ID: 44.621 | |
| SUPPLIER BATCH: ---- | MANUFACTURING DATE: 01/09/2024 | |
| METAPH BATCH: 0020125 | EXPIRY DATE: 30/08/2029 | |

| ATTRIBUTES | SHOULD BE | IS |
|------------------------|---|--------------|
| Appearance | White or almost white powder | White powder |
| Solubility | Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96 %) and in methanol. It dissolves in dilute solutions of alkali hydroxides | Complies (*) |
| Identification | Complies | Complies |
| Appearance of solution | Clear | Clear |
| Impurities F and G | | |
| Sum of the contents | =< 350 ppm | < 350 ppm |
| Absorbance 440 nm | =< 0.10 | 0.08 |
| Related substances | | |
| Impurity D | =< 0.15 % | Not Detected |
| Impurity E | =< 0.15 % | < 0.05 % |
| Unspecified impurities | =< 0.10 % | < 0.05 % |
| Total impurities | =< 0.5 % | < 0.05 % |
| Loss on drying | =< 0.2 % | 0.04 % |
| Sulfated ash | =< 0.1 % | 0.02 % |
| Assay | 99.0 - 101.0 % | 100.6 % |

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Omeprazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the product in airtight containers, protected from light and at a temperature between 2-8 °C.

Analysis date: 20/03/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001056
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